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BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: IM Total Femur

Common or Usual Name: Oncology, Salvage Hip/Knee

Classification Name:
1. Prosthesis, Hip, Semi-constrained, Metal/Polymer, Cemented (21 CFR Part 888.3350)
2. Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer, (21 CFR Part 888.3510)
3. Prosthesis, Knee, PatelloFemorotibial, Semi-constrained, Polymer/Metal/Polymer, cemented (21 CFR Part 888.3560)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Oncology Salvage System (K002757), Salvage/Oncology Hip and Total Femur System (K974558), Maxim® (MCK) Total Knee System (K915132), Biomet SCK Knee System (K003296), AVL Hinged Knee (K010774).

Device Description: The IM Total Femur is, in simplest terms, an intramedullary (IM) rod which connects a proximal hip replacement component to a knee femoral replacement component.

The IM rods are slightly bowed to mimic the natural femur and find appropriate alignment. Both ends of the rod have a male taper for connection to the hip proximal femur and a knee femoral component. Following impaction, a locking screw further secures the parts. Two types of IM rods are available based on the tapers of the distal knee component selected by the surgeon. IM total femur rods with an "Impact" taper at one end and an "OSS" taper at the other come in 1cm increments for replacements of 35cm to 45cm. The second type of rod have an "Impact" taper at both ends and come in 3cm increments for replacement from 34 to 46cm.

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Femoral knee components are available with both "OSS" and "Impact" taper bores. The femoral components articulate with previously cleared tibial bearings, base-plates and patellar components. The device is compatible with any of Biomet's proximal modular hip components.

Intended Use: The device is intended to be implanted with bone cement in cases of:

1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, traumatic arthritis
2. Correction of varus, valgus or post traumatic deformity
3. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement
4. Ligament deficiencies
5. Tumor resections
6. Treatment of non-unions, femoral neck and trochanteric fracture of the proximal femur with head involvement, unmanageable using other techniques
7. Revision of previously failed total joint replacement
8. Trauma

Summary of Technologies: The IM Total Femur components (materials, design and indications) are similar or identical to the predicate devices.

Non-Clinical Testing: Mechanical testing has shown the tapers capable of withstanding expected loading conditions.

Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 6 2004

Ms. Patricia Sanborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K033871
Trade/Device Name: IM Total Femur
Regulation Number: 21 CFR 888.3350, 21 CFR 888.3510, 21 CFR 888.3560
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis, Knee joint femorotibial metal/polymer constrained cemented prosthesis, Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDI, KRO, JWH
Dated: March 22, 2004
Received: March 23, 2004

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033871

Device Name: IM Total Femur

Indications For Use: Total hip and knee joint replacement in cases of:

1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, traumatic arthritis
2. Correction of varus, valgus or post traumatic deformity
3. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement
4. Ligament deficiencies
5. Tumor resections
6. Treatment of non-unions, femoral neck and trochanteric fracture of the proximal femur with head involvement, unmanageable using other techniques
7. Revision of previously failed total joint replacement
8. Trauma

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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